V. GOVERNMENT COSTS

This chapter analyzes the costs to EPA associated with the regulation of microorganisms under the Toxic Substance Control Act (TSCA) as set forth in the rule on microbial products of biotechnology. These costs fall into two categories: operating costs associated with an external peer review subcommittee, and annual costs associated with the review of microorganisms. This chapter is organized into four sections as follows:

- Section A outlines the approach used to determine EPA costs;
- Section B addresses operating costs associated with external peer review;
- Section C discusses the cost of EPA review, including the unit costs associated with EPA's review of a TSCA Environmental Release Application (TERA), Microbial Commercial Activities Notice (MCAN), Tier I and Tier II exemptions, and the expected number of submissions based on the number of microorganisms identified in the survey of biotechnology companies (ICF 1988);
- Section D discusses the cost of current regulatory requirements (baseline costs); and
- Section E presents the quantified cost to EPA resulting from the rule.

A. Overview of EPA Cost Methodology

This section describes the assumptions and methods used to calculate costs to EPA of the rule, including the assumed baseline, the definition of "Year 1" and "Year 5," the data on which external peer review subcommittee and review cost estimates are based, the method used to express review costs, and the submitter fees.

This analysis reports total EPA costs in incremental terms; that is, it uses the current regulatory requirements (1986 Policy Statement) as the baseline.* The total cost estimates for EPA are discussed in terms of "Year

* Intermediate unit cost figures in section C, EPA review, are calculated without consideration of costs under current policy because estimates of these costs are not available.

1" and "Year 5" to maintain compatibility with the industry cost estimates. Year 1 costs are based on the expected costs of review in the early stages of working under the regulation, while Year 5 costs are based on a projection of conditions in a more "mature" stage. Costs in Year 1 and Year 5 are measured as the dollar values for EPA personnel time and other costs where appropriate. Costs are reported as ranges -- "high cost" cases and "low cost" cases-- to account for uncertainty in expectations for both industry and EPA.

Forecasts of time and expenditures for review procedures and meetings of an external scientific peer review subcommittee under the rule are based on information on current Agency activity. Cost data for the rule is based on actual operating expenditures to date of the Biotechnology Advisory Committee (BSAC). The projected review time for submissions received under the rule is based on EPA's experience with reviewing both voluntary and mandatory reporting submissions received under the 1986 Policy Statement.

Costs are calculated for the review of each type of submission (TERA, follow-on TERA, MCAN, Tier I and Tier II exemptions). First, using data gathered from EPA personnel, an estimate is made of the total personnel hours required to conduct the review for a single submission. A review cost per submission is then generated by converting these total hours into a Full Time Equivalent (FTE), assumed to be the cost of a government employee. Agency review costs are then calculated by multiplying the unit cost for review by the expected number of submissions presented in Chapter IV.

To offset the costs of processing each submission, submitters pay a user fee. The fee is authorized by Section 26(b) of TSCA, stating that the Administrator may, by rule, establish fees for persons submitting data under Section 4 or 5 of TSCA to defray the costs of administering TSCA. In 1988, the Agency issued a Final Rule stating that a $2,500 fee would be paid to the

Agency by all those submitting a Premanufacture Notice (PMN) (EPA 1988). A similar scheme has been developed for biotechnology submissions. A submitter will pay $2,500 for a MCAN, but nothing for a TERA, Tier I certification, or Tier II submission. Alternatively, EPA requires a fee of $100 for institutions considered to be small businesses (i.e., sales of $40 million or less) for a MCAN. The $100 small business fee applies as well to chemical submissions.

The user fee per submission is paid by industry to the U.S. Treasury. The fees represent transfer payments (i.e., revenue generated by the U.S. Government through receipt of user fees is equal to the cost to industry of the fees) and therefore, user fees do not represent a net social cost, although they are a cost of doing business for a firm submitting a notification. Thus, the costs to the government resulting from the rule are the incremental costs of the peer review subcommittee meetings and review, less the incremental amount generated from user fees.

B. Peer Review Advisory Subcommittee Costs

The costs associated with the convening of a peer review advisory subcommittee comprise a portion of EPA total costs.* Such an expert panel draws its members from academia, other Federal agencies, biotechnology professionals, and the public. The subcommittee provides EPA guidance on science issues related to biotechnology. Subcommittee meetings called by EPA to provide scientific guidance for the review of microorganisms are an

* Prior to 1995, this panel was known as the Biotechnology Advisory Committee (BSAC), but is now known as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Science Advisory Panel. Costs estimated are based on BSAC reviews, and are judged representative of future review panel costs.

incremental cost to EPA of the rule.* Because current regulations do not require subcommittee meetings, it is assumed that baseline costs are zero. Subcommittees are normally composed of 6 to 9 members that meet as required by EPA. In the past, each meeting, generally has lasted for one day. This analysis assumes that subcommittee meetings in the future also will last for only one day.

The costs of subcommittee meetings are estimated by actual expenditures incurred to date by the BSAC. The Agency is responsible for travel and consulting fees paid to the members, plus the costs of meeting rooms and meeting transcription fees (Ozolins 1990a). Annual BSAC operating costs were derived by calculating the unit cost of a BSAC subcommittee meeting from the items listed above. Unit costs for subcommittees are presented in a range because subcommittee size can vary from 6 to 9 members. Multiplying the unit cost by the expected number of meetings yields the total costs of BSAC subcommittee meetings resulting from microbial reviews under TSCA.

Table V-1 itemizes the per meeting costs that are explained here. EPA pays the travel and lodging for some members. Many members are paid minimal travel expenses because of their proximity to the Washington, DC area. For those members that are paid long distance travel costs, expenses approximate $350 per member per meeting. Some members receive a consulting fee, not exceeding $270 per day, for their services. The Agency also pays for the meeting room, and a court recorder to be present at each meeting. These costs are $930 for conference rooms per meeting, and $1,000 per meeting for the court recorder (Ozolins 1990a). Total meeting costs are shown in Table V-2.

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* The subcommittee may conduct meetings or activities that are unrelated to or not directly attributed to the rule. This analysis assumes that the only costs attributed to the rule are those involving the subcommittee meetings in which "new" microorganism products subject to TSCA are reviewed.

Table V-1. BSAC per Meeting Costs

Unit Costs Per Meeting	Subcommittees 6 members	9 members
Consulting Fee ($270)[a]	$ 810	$1,620
Travel ($350)[b]	$1,400	$2,100
Room Fee ($930)	$ 930	$ 930
Court Recorder ($1,000)	$1,000	$1,000
Total per Meeting	$4,140	$5,650

[a] Assumes 3-6 are paid consulting fees for the Subcommittee.

[b] Assumes 4-6 receive travel and lodging expenses for Subcommittee meetings.

Source: Ozolins 1990a.

In Year 1, it is assumed that subcommittees of 6 to 9 members will be called on for the review of all first time TERA submissions (see Chapter IV) for a total of six meetings. The cost for 6 to 9 members attending these subcommittee meetings ranges from $24,840 to $33,900.

In Year 5, it is assumed that as a result of increased Agency experience, fewer subcommittee meetings will be required. The per member and per meeting fees are expected to remain the same. It is assumed that in Year 5, only 75 percent of first-time TERAs will require the assistance of the peer review subcommittee. The resulting subcommittee cost for Year 5 ranges from $20,700 to $28,250.*

C. Review Costs

The majority of the costs of the rule incurred by EPA are attributable to Agency review of microorganisms. EPA will review information based on the firm's intended use of the microorganism (whether it is to be used in R&D or in general commercial applications and whether it is intended for use in a closed-system) and the nature of the microorganism. Appendix H presents an overview of EPA's review process. The types of reporting mechanisms, the cost per submission review, the number of microorganisms affected, and review costs for each reporting mechanism are presented below. All unit costs in this section are the costs of all review activities required by the rule; that is, all figures reflect a baseline of zero reporting. Total review costs shown in section E are incremental and reflect the costs of the current regulatory environment.

* BSAC costs have been estimated conservatively (specifically, the frequency of BSAC review) due to uncertainties regarding the nature of microorganism submissions. It is assumed that risk will be equivalent for all Year 1 TERAs and that a familiarity factor will reduce BSAC oversight costs by Year 5. Were it possible to categorize anticipated submissions by riskiness, the BSAC oversight requirements could be reduced.

Table V-2. Total BSAC Costs[a]

	Year 1		Year 5	
	low	high	low	high
TERAs (first-time)	6	6	6	6
% With BSAC Subcommittee Meetings	100%	100%	75%	75%
Number of Subcommittee Meetings	6	6	5	5
Cost per Meeting	$4,140	$5,650	$4,140	$5,650
Total	$24,840	$33,900	$20,700	$28,250

[a] Assumes subcommittee review required only in connection with first-time TERA submittals. Meetings have been estimated conservatively because of uncertainties regarding the nature of microorganism submissions.

Sources: Ozolins 1990a, Table IV-3.

1. Submission Review Types

Although the review scheme will be similar for every submission received, there are some differences in review time and emphasis (See Appendix H). Five submission review types corresponding to the regulatory categories identified in the industry cost chapter have been devised to show the difference between the submissions under the rule: TERAs, follow-on TERAs, MCANs, full exemptions (Tier I), and partial exemptions (Tier II).

EPA review of follow-on TERAs or related submissions will be different than the review of submissions that the Agency has never seen before, and it is likely that the time needed for EPA review of a follow-on TERA will be less than the time required for a first-time TERA submission. This analysis assumes, therefore, that the cost of the review for a follow-on TERA is one-third that of a first-time TERA review.* It is expected that follow-ons may comprise a large portion of the reviews undertaken.

For MCANs, it is assumed (as in the Industry Cost Chapter) that at least one TERA will precede every MCAN for a microorganism intended for use outside a contained structure. MCANs for microorganisms intended for environmental application represent the "low cost" case for review of MCANs, because information on health effects and economic consequences will have already been reviewed under the TERA(s) submitted in the microorganism's R&D stage. (A first-time TERA may require more review hours than the MCAN which follows it, even though the designated review period for a TERA is shorter.)

The "high cost" case is assumed to be a MCAN for a microorganism with a fermentation-system application because the Agency may not have seen this microorganism in this particular application before it receives the MCAN.

* This assumption is based on analysis presented in the Industry Cost chapter (Chapter IV).

(TERAs are not required for laboratory or other contained R&D.) Based on the proportions of industry costs, Tier I and Tier II submissions are assumed to cost the Agency 5 percent and 30 percent of the cost of a MCAN full review, respectively, because less information is initially submitted and because, in the case of a Tier I exemption, the certification involves only minimal review.

2. Costs per Review

Data on the time required by EPA personnel to conduct reviews under the rule were obtained from discussion with the individual reviewers, budget materials, and estimates from past activities involving EPA's review of chemical submissions. In some cases, EPA personnel were able to provide a fairly accurate estimate of time they expected to expend on parts of the review. This is because some elements of the review are not new to this rule. In other cases, expected time commitments were more difficult to predict. In these instances, EPA labor and cost estimates are reported as ranges, reflected in the "low cost" and "high cost" estimates (Ozolins 1990b).

The elements of EPA review include technical assessments, meeting attendance, report writing, and the updating of the inventory and databases. Receipt and control of the submission, photocopying, and checking for the completeness of the submission also are accounted for in EPA costs. As well, any post-review activity, such as the negotiation of a conditional approval, or the review of monitoring data requested by EPA are factored into the estimates. The review time also accounts for managerial review, decision meetings, and correspondence between the Agency and submitters. Included in the calculation for TERAs is the time required to negotiate a TERA agreement. As in the Industry Cost Chapter, it is assumed that a TERA Agreement will be placed on every TERA reviewed because there is no means by which to assume

that certain cases would not result in such agreements. The issuance of a TERA Agreement requires additional time by the submission coordinator and EPA lawyers to review monitoring data, if required by the TERA agreement, following a field test, for example. TERA Agreements are expected to take less resources to negotiate than a 5(e) Consent Order.

A "low case" and a "high case" set of unit costs were estimated for the review of each type of submission under the rule. To calculate costs, first, the hours needed by each individual reviewer to complete the designated task, (i.e., conducting a technical review) are estimated. The personnel hours required for each step of the review are then aggregated, yielding the total Agency hours used to complete the review of a single submission. Appendix H presents the breakdown of the personnel hours by submission type and by the EPA divisions responsible for each stage of the review.

Total hours are then converted into full-time equivalents (FTEs); one FTE represents 2080 hours per year. The FTE estimate for each review is the unit time estimate for that task and accounts for all the elements of EPA's review process. It was assumed that government employees would be paid at an average rate of $36,000 - $48,000 per FTE, resulting in a cost range for a fully-loaded FTE of between $75,600 and $100,800. This fully-loaded rate covers salary, and government contributions to retirement, health, life insurance, and other overhead expenses for a senior level analyst (GS-12). Some EPA personnel also estimated extramural costs accounting for technical support provided by an EPA contractor which are added to review costs. Table V-3 shows the steps used to calculate the unit review cost for each submission, and Table V-4 shows the review costs per submission for each submission type.

Table V-3. Calculation of Submission Review Costs for Year 1

Submission Type	Review Costs Low	Review Costs High
1. TERAs		
Total review time (in person hours)	1,251	1,701
FTE Equivalent[a]	0.60	0.82
Personnel cost per submission[b]	$45,360	$82,656
Extramural costs	$ 1,250	$ 1,250
Total submission cost per TERA	$46,610	$83,906
2. Follow-on TERA submission cost[c]	$15,537	$27,969
3. MCANs		
Total review time (in person hours)	848	1,285
FTE Equivalent[a]	0.41	0.62
Personnel cost per submission[b]	$30,996	$62,496
Extramural costs	$ 1,250	
Total submission cost per MCAN	$32,246	$62,496
4. Tier I submission cost[d]	$ 1,612	$ 3,125
5. Tier II submission cost[e]	$ 9,674	$18,749

[a] A full-time equivalent (FTE) is 2080 hours per year.
[b] FTE multiplied by the cost for a fully-loaded senior level analyst (assumed to be $75,600-$100,800).
[c] Based on one-third of TERA cost.
[d] Based on 5 percent of full MCAN cost.
[e] Based on 30 percent of full MCAN cost.

Source: Appendix H.

Table V-4. Unit Review Costs by Submission Type

Type of Submission	Year 1 Low Cost	Year 1 High Cost	Year 5 Low Cost	Year 5 High Cost
1. TERA	$46,610	$83,906	$34,958	$62,426
2. Follow-on TERA	$15,537	$27,969	$11,653	$20,809
3. MCAN	$32,246	$62,496	$24,374	$46,368
4. Tier I	$ 1,612	$ 3,125	$ 1,219	$ 2,318
5. Tier II	$ 9,674	$18,749	$ 7,312	$13,910

Source: Appendix H.

The cost to EPA for each type of review in Year 1 and Year 5 is projected by multiplying the unit review cost by the number of submissions as predicted in Chapter IV. Review costs for Year 1 and Year 5 are presented in Table V-5 and Table V-6.

It is expected that as the Agency gains experience in reviewing microorganisms, the review time will decline, possibly approaching the level of effort for chemical submissions. That is, the development of in-house databases and the increased knowledge gained by Agency scientists will expedite the review process, thereby reducing Agency time commitments for each submission. Thus, to forecast Year 5 costs, this analysis assumes that a 25 percent reduction in review time within the Agency will occur between Year 1 and Year 5 (Ozolins 1990b).

D. Baseline Costs

The costs for review under the current regulatory environment are presented in Table V-7. This baseline was calculated using the number of PMN submissions for environmental and fermentation-system applications (see Appendix D). It was assumed that the Agency review cost of an environmental application PMN is equivalent to the review cost of a first-time TERA, and the review cost for a fermentation-system PMN is equivalent to the review cost of a MCAN. Because review by a peer review subcommittee is not a part of current regulatory requirements, baseline costs for such review are zero.

E. Incremental Costs to EPA for the Final Rule

Table V-8 presents the incremental costs of the requirements of the rule in 1987 and adjusted costs for 1995. The review costs for TERAs, follow-on TERAs, MCANs, and Tier I and Tier II submissions are aggregated, yielding EPA review cost before subtracting baseline costs. The incremental cost of EPA

Table V-5. Gross Costs for EPA Review in Year 1

Cost Element	Expected Costs: Low Cost Case	Expected Costs: High Cost Case
1. TERAs		
Number of Submissions	6	6
Cost per Submission	$ 46,610	$ 83,906
Subtotal Cost	$279,660	$503,436
2. Follow-on TERAs		
Number of Submissions	18	18
Cost per Submission[a]	$ 15,537	$ 27,969
Subtotal Cost	$279,666	$503,442
3. MCANs		
Number of Submissions	4	4
Cost per Submission	$ 32,246	$ 62,496
Subtotal Cost	$128,984	$249,984
4. Tier I exemptions		
Number of Submissions	9	9
Cost per Submission[b]	$ 1,612	$ 3,125
Subtotal Cost	$ 14,508	$ 28,125
5. Tier II exemptions		
Number of Submissions	9	9
Cost per Submission[c]	$ 9,674	$ 18,749
Subtotal Cost	$ 87,066	$168,741
GROSS COST FOR EPA REVIEW IN YEAR 1	$789,884	$1,453,728

[a] Based on one-third of TERA cost.
[b] Based on 5 percent of full MCAN cost.
[c] Based on 30 percent of full MCAN cost.

Sources: Appendix C, Appendix D, and Appendix H.

Table V-6. Gross Costs for EPA Review in Year 5

Cost Element	Expected Costs: Low Cost Case	Expected Costs: High Cost Case
1. TERAs		
Number of Submissions	6	6
Cost per Submission	$ 34,958	$ 62,426
Subtotal Cost	$209,748	$374,556
2. Follow-on TERAs		
Number of Submissions	18	18
Cost per Submission[a]	$ 11,653	$ 20,809
Subtotal Cost	$209,754	$374,562
3. MCANs		
Number of Submissions	6	6
Cost per Submission	$ 24,374	$ 46,368
Subtotal Cost	$146,244	$278,208
4. Tier I exemptions		
Number of Submissions	12	12
Cost per Submission[b]	$ 1,219	$ 2,318
Subtotal Cost	$ 14,628	$ 27,816
5. Tier II exemptions		
Number of Submissions	12	12
Cost per Submission[c]	$ 7,312	$ 13,910
Subtotal Cost	$ 87,744	$166,920
GROSS COST FOR EPA REVIEW IN YEAR 5	$668,118	$1,222,062

[a] Based on one-third of TERA cost.
[b] Based on 5 percent of full MCAN cost.
[c] Based on 30 percent of full MCAN cost.

Sources: Appendix C, Appendix D, and Appendix I.

Table V-7. Baseline Review Costs

Submission type	Year 1 Low	Year 1 High	Year 5 Low	Year 5 High
Environmental Application PMN				
Number of Submissions	2	2	2	2
Cost per submission	$ 46,610	$ 83,906	$ 34,958	$ 62,426
Subtotal Cost	$ 93,220	$ 167,812	$ 69,916	$ 124,852
Closed-System Application PMN				
Number of Submissions	20	20	28	28
Cost per submission	$ 32,246	$ 62,496	$ 24,374	$ 46,368
Subtotal Cost	$ 644,920	$1,249,920	$ 682,472	$1,298,304
Total Cost of Review	$ 738,140	$1,417,732	$ 752,388	$1,423,156

Source: Appendix C.

Table V-8a. Total Government Costs Resulting from the Final Rule
(1987 Dollars)

Type of Cost	Year 1 Low	Year 1 High	Year 5 Low	Year 5 High
External peer review				
Final Rule	24,840	33,900	20,700	28,250
Baseline	0	0	0	0
Incremental Costs	$ 24,840	$ 33,900	$ 20,700	$ 28,250
Agency Review				
Final Rule	789,884	1,453,728	668,118	1,222062
Baseline	738,140	1,417,732	752,388	1,423,156
Incremental Costs	$ 51,744	$ 35,996	(84,270)	(201094)
Total Net Cost to EPA	$ 76,584	$ 69,896	(63,570)	(172844)
User Fees Paid to US Treasury				
Final Rule	10,000	10,000	15,000	15,000
Baseline	55,000	55,000	82,500	82,500
Incremental Costs[a]	(45,000)	(45,000)	(67,500)	(67,500)
Net Government Cost	$121,584	$114,896	3,930	(105,344)

Note: Because the relative difference for the high cost case is smaller than for the low cost case, high and low cost estimates are reversed.

[a] User fee costs represent a net cost to the Government because the current policy would generate higher user fee revenue than the final rule.

Sources: Tables V-2, V-5, V-6, and V-7, Appendix D.

Table V-8b. Total Government Costs Resulting from the Final Rule
(1995 Dollars)

Type of Cost	Year 1 Low	Year 1 High	Year 5 Low	Year 5 High
External peer review				
Final Rule	33,683	45,968	28,069	38,307
Baseline	0	0	0	0
Incremental Costs	$ 33,683	$ 45,968	$ 28,069	$ 38,307
Agency Review				
Final Rule	1,071,083	1,971,255	905,968	1,657,116
Baseline	1,000,918	1,922,445	1,020,238	1,929,799
Incremental Costs	$ 70,165	$ 48,811	(114,270)	(272,683)
Total Net Cost to EPA	$ 103,848	$ 94,779	(86,201)	(234376)
User Fees Paid to US Treasury				
Final Rule	13,560	13,560	20,340	20,340
Baseline	74,580	74,580	111,870	111,870
Incremental Costs[a]	(61,020)	(61,020)	(91,530)	(91,530)
Net Government Cost	$164,868	$155,799	5,329	(142,846)

Note: The Regulatory Impact Analysis of Regulations on Microbial Products of Biotechnology prepared on January 14, 1994 presented costs in terms of 1987 wage rates. These values have been revised to reflect current wage rates. Specifically, government costs for selected regulatory options were updated based on estimated increases in labor category cost estimates between March 1987 and June 1995.

According to the Bureau of Labor Statistics Employment Cost index, the average percent rate of increase in total compensation between March 1987 and June 1995 was 35.6% (BLS 1995). This value was used to inflate values for Year 1 and 5 of the quantified government costs of selected regulatory options in this table.

Because the relative difference for the high cost case is smaller than for the low cost case, high and low cost estimates are reversed.

[a] User fee costs represent a net cost to the Government because the current policy would generate higher user fee revenue than the final rule.

Sources: Tables V-2, V-5, V-6, and V-7, Appendix D.

review is then calculated by subtracting away the baseline review cost from this total. This method was used because environmental and closed-system PMNs, the baseline reporting mechanisms, do not directly compare to TERAs, follow-on TERAs, MCANs, Tier I and Tier II Exemptions, the rule's reporting mechanisms.

The incremental costs to EPA of the rule are BSAC costs and Agency review costs minus the costs of BSAC and Agency review under the current regulatory requirements. Government costs as a result of the rule are then calculated by adding in the net revenue generated from user fees (a user fee of $2,500 is paid to the Agency for each PMN submission under current regulatory requirements, and for each MCAN submission under the rule).* Government costs in Year 1 resulting from the rule range from $114,896 to $121,584 in 1987 dollars and between $155,799 to $164,868 in 1995 dollars. Savings in Year 5 resulting from the rule may reach $105,344 in 1987 dollars or $142,846 in 1995 dollars. **

* Small businesses would be required to submit a user fee, as well. User fees for small businesses are $100 per submission. The analysis presented in this RIA assumes that all MCANs would incur the full cost of $2,500 per submission.

** Because the relative difference for the high cost case is smaller than for the low cost case, high and low cost estimates as shown in Table V-8 are reversed.